DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857



FEB 4 2002

Novex Pharma
Attention: Dawn Culp
Manager, Regulatory Affairs
380 Elgin Mills Road East
Richmond Hill, Ontario
Canada L4C 5H2

RE: Docket No. 98N-0337
Applications for Exemption
APP 38 and APP 39

Dear Ms. Culp:

We are responding to your applications for exemption, dated November 15, 2001, for a temporary deferral of the implementation of the requirements of 21 CFR 201.66(c) and (d) for the following over-the-counter (OTC) drug products:

| Application No. | ANDA No. | Product |
|---|---|---|
| APP38 | 74-924 | Minoxidil Topical Solution 2% |
| APP39 | 75-839 | Minoxidil Topical Solution 5% for Men |

You stated a number of reasons to support your request, which we are not restating here.

In your applications for exemption, you requested a deferral of the following time periods based upon the date of availability of the final agency Drug Facts labeling template or approved reference listed drug (RLD) labeling in Drug Facts format:

| Labeling Availability Date | Deferral Requested |
|---|---|
| 11/01/2001 to 11/30/2001 | 60 days |
| 12/01/2001 to 12/31/2001 | 90 days |
| 1/01/2002 to 1/31/2002 | 120 days |
| 2/01/2002 to 2/28/2002 | 150 days |
| 3/01/2002 to 3/31/2002 | 180 days |
| 4/01/2002 to 4/30/2002 | 210 days |
| 5/01/2002 to 5/31/2002 | 240 days |

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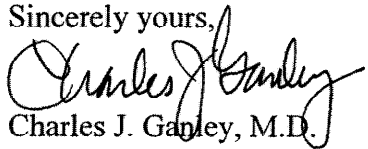
You stated that at the time that approved RLD labeling in Drug Facts format or a final FDA template becomes available for each product, your company will file a Changes Being Effected (CBE) Supplement for approval of the new labeling in the relevant ANDA and the product will then be entered into your labeling conversion schedule. You added that due to the length of time required to prepare labeling, submit a CBE Supplement, and finally convert the product labeling, you anticipate that conversion for a particular product can be accomplished approximately 6 months from the filing of the supplement, assuming no changes are required following agency review of the Supplement.

Based on the time that it has taken to finalize current FDA Drug Facts template labeling for ANDA drug products and the anticipated availability of the additional template labeling, as noted above, we consider your timetable for concurrent implementation of labeling revisions for these OTC drug products to be appropriate. Accordingly, we are granting deferrals, as a matter of enforcement discretion, for APP 38 and 39 in accord with your requested deferral schedule. These deferral times would be the number of additional days that would be allowed after May 16, 2002, to comply with the new Drug Facts labeling requirements. For APP 38 (Minoxidil Topical Solution 2%), the number of days would be determined based upon the date of availability of the revised agency Drug Facts labeling template. For APP 39, the number of days would be determined based upon the date of availability of the new Drug Facts labeling template that the agency is developing or the date of approved reference listed drug (RLD) labeling in Drug Facts format, whichever occurs first.

If you have any comments or questions regarding these deferrals, please reference the docket and application for exemption numbers and submit them to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. I hope this information is helpful.

Sincerely yours,



Charles J. Ganley, M.D.
Director
Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

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DATE: 2.4.02

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 98N-0337

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[ ] This material should be cross-referenced to Comment No. _____

Charles J. Ganley, M.D.

Attachment